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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,412	HON ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/06/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-25 are pending in the application and were examined on the merits.

Continued Examination

It is noted that the Instant application appears to contain New Matter contained in claim 23 (please see rejection under 35 USC 112 First paragraph *infra*). Because the specification contains New Matter, the Instant application is not a proper continuation, but rather a CIP of 09/716,890. Further, because this application is a CIP of '890, a new Oath or Declaration must be established for the CIP.

Specification

The Specification is objected to for identifying the Instant application as a continuation of 09/716,890. As it is established in the proceeding rejection under 35 USC 112 First paragraph, claim 23 appears to contain New Matter. If this matter is not found within the originally filed application, and Applicants wish to keep this matter in the claims, then the Specification should reflect that this is a CIP of '890 and should be amended accordingly.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28 and 30-31 of copending Application No. 09/716,890. This is a provisional obviousness-type double patenting rejection. In the Instant case, Claims 28, 30 and 31 of '890 teach a method for enhancing wound healing comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions. The claims of '890 do not specifically teach wherein the pH has a range of approximately 4-7, or

wherein the pharmaceutically acceptable carrier is selected from ointments and creams for example

However, the Specification of '890 which is the parent case to this Instant application, clearly teaches that the preferred pH of the compositions are 4-7 (p.4) and that carriers such as ointments and creams were suitable for use in the composition (p. 4). Thus, the Instant claims are obviated by '890.

Claims 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-5 of U.S. Patent No. 6,149,947 A. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons: Claims 22-25 are obviated by claims 1-5 of '947. Although the claims of '947 do not specifically state wherein the pH of the composition is approximately 4-7, or wherein the pharmaceutically acceptable carriers comprise ointments or creams for example, '947 clearly teaches that that the preferred pH of the compositions are 4-7 (p.4) and that carriers such as ointments and creams were suitable for use in the composition (p. 4). Thus, the Instant claims are obviated by '947.

Claim Objections

Claim 23 is objected to because of the following informalities: Claim 23 recites 'creams hydrogels'. A comma (,) should appear between these two words. This is considered a minor grammatical error.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, carriers comprising hydrogels, alginates and kerosol were not found in the Instant specification and therefore these embodiments are considered New Matter. Applicant is asked to either 1, delete the new matter from the claims, or 2) point out the exact location of each of the embodiments in the Instant specification as filed.

Claims 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis or acne (what was already known in the art), does not reasonably provide enablement for treatment of all of the skin disorders as listed in claim 25, or broadly to any skin disorder as recited in claim 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicants are claiming numerous skin conditions which may be treated with a composition comprising rubidium and potassium ions, but have not provided any evidence of such in the Instant specification. It is noted that there is *not a single example in the Instant specification*, working or prophetic, which indicates that the product of the Instant claims; i.e., containing only rubidium and potassium for example disclosure would perform beneficially on any type of HVS originated skin disorders, cancerous ulcers, cancers, scars, psoriasis, wrinkles or any of the claimed disorders in claim 25. Although Applicants provide some examples in the Instant specification, these are not considered *'Working Examples'* because they do not correlate with the

scope of the Instant claims which state that only potassium and rubidium can be used. On the contrary, the examples in the Instant specification are mainly drawn to wherein an 80% extract of oak bark was used as the active ingredient Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of record.

Further, the instant specification provides absolutely no reasonable extrapolation to a known method for using minerals in treating acne and psoriasis with more aggressive skin disorders such as herpes simplex II caused by the HSV-II virus for example or cancerous ulcers. No mechanism of action has been established for the claimed composition and thus, a reasonable correlation cannot be achieved which would lead the skilled artisan to have any expectation that the composition would work for the claimed disorders.

The state of the art is unpredictable as it reflects that there is no cure for cancer and cancer treatments are rare. Bally et al. (US 5,595,756) stated, " Despite enormous investments of financial and human resources, no cure exists for a variety of diseases. For example, cancer remains one of the major causes of death. A number of bioactive agents have been found, to varying degrees, to be effective against tumor cells. However, the clinical use of such antitumor agents has been highly compromised because of treatment-limiting toxicities" Bally et al. (Col.1 lines 17-24). It is noted that

the term 'prevention' is deemed to be a 'cure' because prevention of a disease state is broad enough to encompass complete inhibition; i.e., curing.

Therefore, in order to perform the methods as Instantly claimed would not just require a repetition of Applicant's work, but would entail a considerable amount of inventive contribution on the part of the skilled artisan involving undue experimentation. This experimentation would be undue considering that the skilled artisan would not have any reasonable expectation of success in carrying out the scope of the claimed invention due to lack of guidance in the specification with regard to the efficacy of the composition of the claims toward the claimed ailments as well as lack of teachings in the art with regard to the effectiveness of the claimed composition toward all of the claimed ailments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Carmel, A. (8/1991) in light of Genis et al. (US 6,458,338)*.

Carmel, A. (8/1991) disclosed a composition sold by Orris Pharmaceuticals comprising dead sea minerals in products such as hand and foot creams, body lotion, shampoo and bath salts (see p. 5). The article also states that the minerals will treat psoriasis, acne or 'other skin conditions' (p. 5, last paragraph).

Dead sea minerals contain rubidium and potassium as evidenced by Genis et al. (US 6,458,388 B1)(see col.2, lines 63-67 and Table 1, col. 3).

*this reference is being cited merely to relay an inherent property of dead sea minerals and is not used as a basis for rejection *per se*.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Genis et al. (US 6,458,388 B1).

Genis et al. disclosed a cosmetic cream that contained dead sea salt that comprises rubidium and potassium ions (again, please see col.2, lines 63-67 and Table 1, col. 3).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

07/16/04